

More Relators Push FCA Cases To The End In 2017

By **Daniel Wilson and Jeff Overley**

Law360, Nashville (January 4, 2018, 9:02 PM EST) -- While the \$3.7 billion in False Claims Act recoveries made in fiscal 2017 is unremarkable in comparison to some recent record years, a look behind that figure shows some more interesting trends, including what looks to be relators' greater willingness to pursue cases to their end without government assistance.

The U.S. Department of Justice released its fiscal 2017 FCA figures on Dec. 21, saying it had recovered a little more than \$3.7 billion from related settlements and judgments for the year, about \$1.1 billion less than what it recovered in 2016.

But not much should be read into this billion-dollar drop, attorneys said, arguing that the absence of just one or two big recoveries in any given year can make all the difference.

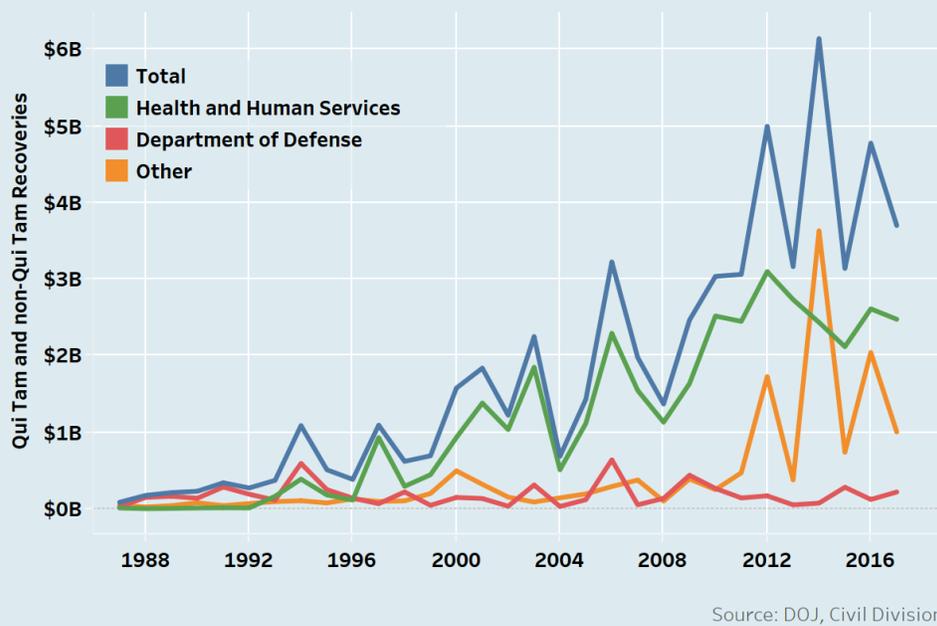
"The numbers, once you normalize for the fact that they're short of one blockbuster recovery this year, are roughly in line with prior years," Vinson & Elkins LLP partner Craig Margolis said. "If they hit the DOJ lottery on a giant recovery, then the numbers tend to be a little larger, but it tends to be a fairly small percentage of cases that drive the biggest numbers."

The largest single federal FCA recovery in fiscal 2017, for example, was the \$343.9 million paid by Shire Pharmaceuticals LLC to resolve claims of alleged off-label marketing and kickbacks paid to doctors and clinics related to its bioengineered human skin substitute. In comparison, the largest recovery in 2016 was a \$1.2 billion mortgage fraud settlement involving Wells Fargo, one of several huge mortgage fraud deals in recent years

Attorneys also noted that a \$3.7 billion recovery total only looks low, as FCA recoveries are trending at an all-time high. Annual recoveries haven't dropped below \$3 billion since 2010, a threshold that had only been hit once previously, in 2006. More than half of the nearly \$56.2 billion recovered under the law since 1986, when lawmakers significantly amended the statute to encourage its use, has come since 2010.

FCA's Wide Reach On Display

2017 saw the fourth-largest annual haul for FCA cases, and sizable settlements affected a wide range of industries.



As has been common across most of that period — with the exception of 2014, which had a record \$6.15 billion total recovery, driven by \$3.1 billion in recoveries from mortgage fraud cases stemming from the 2008 financial crisis — the health care industry was responsible for the majority of FCA recoveries in 2017, or just under \$2.48 billion. A broad range of suits ranging from defense to mortgage fraud issues made up the remainder.

But even within the well-worn area of health care fraud recoveries, new ground continues to be broken, attorneys said, pointing to a first-of-its-kind \$155 million settlement with eClinicalWorks over alleged false certification of ECW's electronic health records, or EHR, software as compliant with federal drug coding standards.

"[That] case, to us, has stood out as signaling a new area that we think the government will continue to be interested in," Phillips & Cohen LLP partner Claire Sylvia said.

Another FCA settlement that broke new ground in 2017 was a \$465 million deal — \$231.7 million of that involving federal claims — reached by Mylan over allegedly misclassifying its brand-name EpiPen drug as a generic to avoid paying a higher rebate, Getnick & Getnick LLP managing partner Neil Getnick said.

In that case, the relator was not an employee or former employee of the company, as is most common, but instead a rival drugmaker, Sanofi-Aventis. It will be interesting to see if other companies similarly refuse to "stand by and watch themselves get outcompeted by those who are violating the law," Getnick said.

"That really, in my view, is the single most important [FCA] lesson of 2017, and the real question now ... is whether other companies will follow suit and take that leadership role," he said.

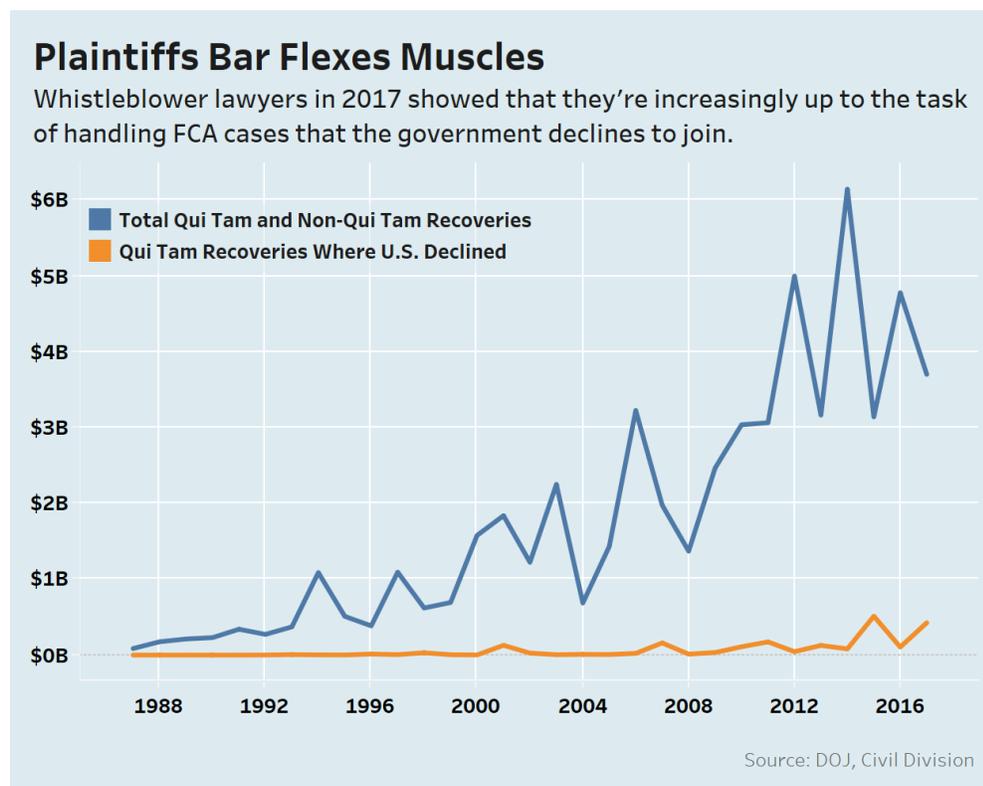
And while defense-related FCA recoveries continue to make up only a small percentage of overall FCA recoveries, or about \$220 million in 2017, an uptick in those cases brought directly by the government in 2017 — 19, up from nine in 2016 — could be another trend to watch, Crowell & Moring LLP partner Tully McLaughlin said.

“The DOJ itself filed double the number of cases that it did the year before and essentially double the amount it’s filed in each of the last four years or so. ... Looking ahead, it’ll be interesting to see whether that is the start of a trend,” he said.

One further aspect of those 2017 figures that deserves attention is how much of the \$3.7 billion was driven by relators, several attorneys said. Although whistleblower suits always make up the vast majority of FCA cases, because of factors such as limited government resources, 2017 still marked an unusually high overall recovery from relators’ cases, they said.

Just \$265.6 million recovered in 2017 stemmed from cases that weren’t brought by qui tam relators, the lowest such total since the \$169 million in non-qui tam recoveries made in 2013. As a point of comparison, 2012, 2014 and 2016 each had at least \$1.6 billion in recoveries stemming from non-qui tam cases, and in 2015 about \$730 million came from non-qui tam cases.

And the amount of recoveries driven by relators continuing to pursue their cases even after the government declined to intervene was also unusually high, attorneys said. About \$425.8 million in 2017 recoveries came from relators continuing to push their nonintervened cases, most prominently a \$280 million settlement with Celgene Corp. over off-label marketing claims.



That was the second-highest annual amount ever recovered from such cases, behind the \$512.3 million collected in 2015 — the next highest amount recovered through nonintervened cases in a single year

was \$173.9 million in 2011 — and gives relators hope that they can successfully pursue FCA claims they believe are worthy, even without government help, according to Sylvia.

“The government can’t do all the cases, even all the good cases, and private lawyers should be able to take good cases and pursue them,” she said. “And they are.”

For FCA defendants, that means they can’t simply “presume that the matter is going to go away if the government elects to decline,” Epstein Becker Greenhealth care and life sciences practice chair George Breen said.

Several attorneys, however, said they would take a wait-and-see approach on the issue. Just as one blockbuster recovery can skew a year’s overall FCA numbers, one large nonintervened settlement like the Celgene deal can similarly skew those numbers, and the majority of FCA recoveries still involved the government intervening to use its leverage, they said.

Attorneys also warned against taking a single year’s figures as indicative of any change in FCA policy under the Trump administration, for several reasons. FCA cases, for example, aren’t typically resolved until several years after they’re filed, and while the direction of FCA enforcement can be nudged by DOJ brass, it is driven largely by attorneys in its civil fraud section, most of whom are long-term staffers, they said.

A continued focus on individual accountability in 2017 that began under the so-called Yates Memo, highlighted by the DOJ when it released its figures, is just one example of the continuity that exists between administrations, they said.

“If people are trying to read the tea leaves and say, ‘Oh look, the numbers are down, the Trump administration is not going to be strong on FCA enforcement,’ I think — I’ll use a strong word — I think that’s nonsense,” Margolis said. “The government makes too much money off of the False Claims Act. ... I anticipate cases will hum along at a good pace.”

Perhaps most importantly, although the DOJ can choose which whistleblower cases it wants to put its resources into, the direction of FCA cases, as a whole — as the 2017 figures clearly lay out — is effectively driven by relators, not the government, attorneys noted.

“It’s a whistleblower-driven area,” McLaughlin said. “And the incentives continue to be there [for relators] — you can see that in the recovery and relator share figures and in the number of cases that continue to be filed.”

--Editing by Mark Lebetkin and Breda Lund.

